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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,705	10/07/2003	Gregory B. Altshuler	105090-194	2638
21125	7590	11/25/2005		
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER JOHNSON III, HENRY M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/680,705	Applicant(s) ALTSHULER ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 39-68 is/are rejected.
- 7) ☒ Claim(s) 36-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0204 0304 1204 070</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the limitation "said cooling" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "said cooling" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "cooling" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9-14 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication US 2001/0023363 to Harth et al. Harth et al. teach a device for treatment of acne with radiation with a wavelength of 405 to 440 nanometers to induce the porphyrins to produce oxygen. The process is interpreted as biostimulation. Treatment times are disclosed as 15, 30 and 60 minutes. A fan is disclosed that serves to cool and remove

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access heat (control temperature) from the treated skin area (paragraph 0058), the fan being an independent source. The intensity on the skin area is disclosed in the range of 10 mW/cm² to 500 mW/cm² (paragraph 0030) and the beam is diverging at a small angle and creates an oval shaped illumination area of typical size 20X10 cm (paragraph 0071) which yields an area of 200 cm². The intensity over a 15 minute interval yields a fluence of 9-450 J/cm².

Claims 1, 2, 5, 9-14, 16 17 20-22 26, 27, 29-31 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,707,401 to Talmore. Talmore teaches a device for combining hyperthermic therapy and photodynamic therapy and that combining the two therapies provides benefits (Col. 1, lines 60-67). The treatment consists of radiation with a wavelength of 600-750 nanometers and an intensity of 100-150 mW/cm². An Xe lamp provides radiation in the stated wavelengths and heating is provided by a CO₂ or Nd:YAG laser (Col. 3, lines 40-49). Nd:YAG lasers typically emit light with a wavelength of 1064 nm, in the infrared. However, there are also transitions near 940, 1120, 1320, and 1440 nm. Heating a treatment area to from 41 to 46°C is disclosed with a total treatment time of 20 minutes (Col. 3, lines 29-32), however, the non-heating therapy can be as little as five minutes. 100 mW/cm² for five minutes yields a fluence of 30 J/cm². Talmore discloses the treatment depth as from 3 to 7 millimeters. Talmore clearly teaches a relation between temperature and efficiency of radiation treatment by disclosing the power may be reduced when the temperature of the tissue is elevated. The implied corollary is that reduced temperatures inhibit efficiency.

Claims 1, 7, 8, 23-25 62-65 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,099,521 to Shadduck. Shadduck teaches a device for biostimulation (Col. 20, line 29) including a laser and a contact lens with a Peltier element for cooling an eye before, during or after radiation (abstract). The laser inherently has a narrow bandwidth. The Peltier element is an independent source for cooling. Since it is disclosed the cooling may be before any

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radiation and the normal body temperature is 37°C, it is inherent the temperature would be reduced below 36°C. Shadduck further teaches closed loop control using temperature sensors (abstract), inherently requiring a set point which is a predetermined threshold.

Claims 48-57 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,267,779 to Gerdes. Gerdes discloses a device for photobiostimulation (Col. 1, line 40) that includes multiple radiation sources in the wavelengths of 400-700 nanometers and 900-1100 nanometers (Col. 5, lines 24-34) connected to wands via fiber optic cables (guidance device). The wands deliver the radiation to a treatment area and include lenses for focusing the beam size (Col. 8, lines 25-30), and may include a fresnel lens (Col. 9, line 47). The infrared radiation is controlled and capable of heating and therefore is interpreted as capable of controlling the temperature of a region. The radiation sources are diode lasers with an inherent narrow bandwidth and are monochromatic. The intended use of the beam (biostimulation) is not limiting to the structure of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, and 32-34 39-47 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0023363 to Harth et al. in view of U.S. Patent 6387089 to Kreindel et al. Harth et al. are discussed above, but do not teach a wavelength of 760-880 nanometers, scanning or controlling a temperature using thermal contact. Kreindel et al. disclose an apparatus and method for wrinkle smoothing using radiation with a range of 600-1600 nanometers (Col. 2, line 36) and cooling the treated area with ice, a gel or a crystal in contact with the surface (abstract). Ice is interpreted as a having a surface and a gel is interpreted as a cream. Kreindel et al. also teaches scanning the radiation over the treatment area (Col. 6, lines 57-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wavelengths, scanning and cooling methods of Kreindel et al. in the invention of Harth et al. as it is well known that the wavelength determines the depth of tissue penetration and the cooling using external substances is likewise well known, so one skilled in the art would be motivated to use whichever best suited the application.

Regarding claim 39, ice applied controls the temperature and inherently modulates the biostimulation.

Regarding claim 68, the number of exposures (scans) is not disclosed as critical and is specifically indicated as an alternative step. Inducing biostimulation is accomplished with any number of scans or passes over the treatment area.

Claims 18 and 19 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,707,401 to Talmore. Talmore is discussed above, but does not teach the use of ultrasonic or microwave for heating or broadband source for a separate heating source. Both

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ultrasonic and microwave energy is known to induce heating and these are therefore considered alternative equivalent heating energy sources. Talmore teaches a separate heating source as a laser, however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a broadband source as an alternative as the control is less complex.

Claims 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,267,779 to Gerdes as applied to claim 48 above, and further in view of U.S. Patent 6,605,083 to Clement et al. Gerdes is discussed above, but does not teach the use of a beam splitter or reflectors. Clement et al. discloses a device for directing radiation to a tissue area wherein a source beam is split into a plurality of beams (Fig. 3, #s 11 & 12) and the beams are then directed to a surface with reflectors (Fig. 3, #s 13 & 14). The use of optical elements in light applications is pervasive providing motivation to look to such devices for radiation delivery and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the beam splitter and reflectors as taught by Clement et al. in the invention of Gerdes to deliver the beam to the treatment area.

Regarding claim 59, it is directed to intended use.

Regarding claims 60 and 61, a prism is well known as a beam splitter and is considered an alternative equivalent. Similarly, reflectors are well known and used in various configurations including flat, parabolic, hyperbolic and other curved shapes. The selection of the appropriate shape would be obvious to one skilled in the art.

Allowable Subject Matter

Claims 36-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Biostimulation of tissue occurs by exposure to virtually any radiation. Low levels may not produce measurable results, but biostimulation has occurred. For extremely high fluences, tissue destruction may occur, however, in the process biostimulation also occurs. Thus the term biostimulation may be very broad in its interpretation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Patent Examiner
Art Unit 3739